

Remarks:

Reconsideration of the application is requested. Applicant submitted a Response to Office Action July 20, 2009. As set forth in the Notice of Non-Compliant Amendment, the listing of claims was not consistent with the discussion of claims in the Remarks section. Accordingly, this Response addresses the non-compliance of the previously submitted Response and represents the previously made claim amendments and arguments.

Claims 1, 4-10, 13, 15, 19, 30-33, 35, 37-39, 41, and 46-50 are now in the application. Claims 1, 15, 19, 30-34, 38, 41, and 46 have been amended. Claims 43 and 45 have been canceled; claims 2-3, 11-12, 14, 16-18, 20-29, 34, 36, 40, 42 were previously canceled. Claim 33 has been withdrawn. Claims 47-50 are new.

35 USC § 101

In the third paragraph on page two of the Office action, the Examiner rejected claims 43-46 as being drawn to non-statutory subject matter. Claims 43-45 have been canceled and claim 46 has been amended to depend from claim 41. The claims were not canceled for reasons relating to the Section 101 rejection. The claims were canceled because they had similar scope to other claims pending in the application. In this regard, Applicant notes that no part of the human body is positively claimed. The bones described in the claims are never positively claimed. Rather, the bones are the work piece with which the positively claimed device interacts. See MPEP § 2115. The bones are only inferentially introduced and not positively claimed. Accordingly, the claims do not positively claim natural subject matter.

Applicant notes that no prior art was cited against claim 46. As Applicant has addressed the Section 101 rejection, Applicant respectfully submits that claim 46 is now allowable.

35 USC § 103(a)

In the second paragraph on page three of the Office action, the Examiner rejected claims 1, 8-9, 13, 15, 19, 30-32, 35, 37-39, 41, and 43-45 as being obvious over Stone '433 in view of Michelson '635 and Henderson et al. '175 under 35 U.S.C. § 103(a). The rejection has been noted and the claims have been amended in an effort to define more clearly the invention of the instant application.

As an initial matter, Applicant notes that all three of the references have been discussed in prior Responses. This discussion is incorporated herein by reference and will not be repeated in this interest of brevity.

Stone '433 teaches an osteotomy device. The device is a wedge shaped member with two inclined surfaces.

The osteotomy device according to Stone '433 is placed into an open incision in a single bone. The osteotomy device is not inserted into a joint. The device is secured in place at a superior location on the bone and at an inferior location on the bone.

None of the embodiments of the device in Stone '433 teach a device as provided in claims 30 and 41 of the instant application. The wedge device according to the invention recites, *inter alia*, the "second surface and the implantable device having no fastener to hold in place mechanically the implantable device to the second bone when completely installed."

In contrast, in the embodiment shown in Figs. 1A and 1B of Stone '433, "At a minimum, at least one of the principal surfaces 112, 114 is adapted, at least in part, to engage mechanically a surface or surfaces thereto. ... Preferably, both surfaces 112, 114 are adapted, at least in part, to engage mechanically surfaces adjacent thereto. ... In particular, the shapes, surface textures and/or materials of the principal surfaces 112, 114 are adapted to mechanically engage adjacent surface materials such as bone." See Col. 5, line 65, through col. 6, line 13. "In another exemplary embodiment, as shown in FIG. 2A, the saw-tooth surface textures of the principal surfaces 112 and 114 are adapted to mechanically engage surfaces adjacent to the body 110."

See col. 6, ll 21-24. “In still other exemplary embodiments, one or both of the principal surfaces 112, 114 are formed of a material selected to engage mechanically surfaces adjacent to body 110.” Col. 6, ll 21-23. “In alternative embodiments, the material of one or both of the principal surfaces 112, 113 includes roughened non-porous material which has properties which facilitate the binding of bone to the principal surfaces 112, 114.” *See* col. 6, 40-44. “In still a further embodiment, the substantially wedge-shaped body 110 can be further secured with a screw and plate system, as illustrated in FIG. 2B.” Col. 6, ll 64-66.

Despite the wording in Stone ‘433 (i.e. “at least one surface”), in practice an osteotomy device must be secured on both the superior and inferior surfaces. As discussed in Applicant’s Declaration under Rule 1.132 submitted June 12, 2007, one of ordinary skill in the art, such as an orthopedic surgeon, would know that an osteotomy device needs to be fixed on both sides to the bone in which the device is inserted. Furthermore, an orthopedic surgeon and one of ordinary skill in the art would know this regardless of ambiguous language used in Stone ‘433. So even though Stone ‘433 might mention “at least one surface being porous” one with ordinary skill in the art reading Stone ‘433 would still know that the device is to be fastened in at least some form on both its superior and inferior surface.

In contrast to the prior art, the invention according to claims 30 and 41 describes a device inserted between two bones of a joint where one of the bones is free to articulate against one of the surfaces of the device. To facilitate the articulation, the device according to claims 30 and 41 describes a structure that is particularly suited to this purpose: i.e. “Said second surface and the implantable device having no fastener to hold in place mechanically the implantable device to the second bone when completely implanted.”

Stone ‘433 does not teach or suggest an implant that has one surface that is fixed with respect to one of the bones of a joint and another surface that is not held mechanically to the other of the bones in the joint. Although the Examiner is correct in noting that Stone teaches that no fasteners need to be used, Stone does not teach that only one fastener can be used. The simple reason for this is that Stone is an osteotomy wedge, which is used to fuse two portions of the

same bone. Any relative movement between the two portions could have adverse clinical consequences for the patient.

Likewise, Henderson et al. '175 teaches an implant with a porous surface or smooth-but-fastened surface for immobilizing both sides of a joint. Michelson et al. '635 teaches a porous implant for encouraging bone in-growth that is used to immobilize both sides of a joint. In summary, Henderson and Michelson are both fusion devices, with no movement between the two bones, while the instant invention permits movement between the two bones.

In addition, Stone in view of Michelson and Henderson does not suggest the invention according to claims 30 and 41. The invention according to claims 30 and 41 is more than a combination of the devices with a removal of a fastener from one of the surfaces. The invention according to claims 30 and 41 recites structures that are not suggested by the prior art: a surface that moves relative to a bone and another surface that is fixed relatively to a second bone. In addition, this surface is not held in place mechanically (i.e. fasteners, serrations, pores, roughen surface). The prior art teaches a device that is either smooth and secured with a fastener or a rough surface that is mechanically held by the surface qualities. In both situations, the devices suggested by the prior art are not applicable to a joint wherein one bone is left to articulate relative to the implant.

Accordingly, none of the references, whether taken alone or in any combination, either show or suggest the features of claims 30 and 41. Therefore, claims 30 and 41 are patentable over the art. And, because all of the dependent claims except for claim 46 are ultimately dependent on claim 30, they are believed to be patentable as well at least for the same reasons. Claim 46 is believed to be patentable at least for the same reasons as claim 41.

Claims 47-50 have been added to distinguish the prior art further. Claims 47-50 describe the wedge device and how it is configured to contact the bones during the insertion process. The wedge shape is intended to be the device that changes the positions of the bones in relation to each other. Accordingly, the bones contact the surfaces of the wedge device in both the initial position and in the spread position. In contrast, Stone '433 for example shows a device that is inserted into an incision. The implant does not contact the bone in the narrow position and is not

used to change their position. In Stone '433, the implant is used to support the bones in their wide position.

Related cases:

Applicant notes that serial number 10/756,001 is a related case involving method claims. Applicant added the phrase "when completely installed" to claim 30 to prevent rejections based on a prior-art device being partially (i.e. one surface) installed.

Interview Request:

Applicant requests a telephonic interview with the Examiner to discuss the claims as amended. The Examiner is asked to telephone the undersigned attorney to arrange an appointment for the interview.

Conclusion:

In view of the foregoing, reconsideration and allowance of all pending claims are solicited. In the event the Examiner should still find any of the claims to be unpatentable, please telephone counsel so that patentable language can be substituted.

All fees believed to be due were paid with the prior Response. No additional fee is believed due. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 780-A03-021-5).

Respectfully submitted,

/Paul D. Bianco/

Paul Bianco, Reg. No. 43,500
Customer Number: 33771
FLEIT GIBBONS GUTMAN BONGINI & BIANCO, P.L.
21355 East Dixie Highway
Suite 115
Miami, FL 33180
Tel: 305-830-2600; Fax: 305-830-2605
e-mail: PBianco@FGGBB.com